

**REMARKS**

This paper is filed in response to the non-final Office Action dated December 21, 2004. Claims 1-63 were pending. Claims 1, 11, 17, 26, 38, 39, 51 and 58 have been amended to more particularly point out and define the claimed invention. Due to a typographical error, two consecutive claims were designated as "Claim 59." Accordingly, one of these claims has been canceled herein, and added as new Claim 64. Claim 25 is objected to as dependent upon a rejected base claim. Accordingly, new Claim 65, which constitutes Claim 25 (canceled herein) written in independent form, has been added. No new matter has been added by these amendments. As such, Claim 1-24 and 26-65 are pending.

**Double Patenting Rejections**

Claims 1-3, 21 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-4 of U.S. Patent No. 6,706,024. Additionally, Claims 1-24 and 26-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-22 of copending Application No. 09/746,670. In response, Applicants submit herewith a terminal disclaimer that, with respect to each of these patent documents, disclaims the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §§ 154 to 156 and 173. Accordingly, Applicants respectfully request that the rejections of double-patenting be withdrawn.

The Examiner has requested a copy of the claims currently pending for Application No. 09/618,432 to review for potential double patenting issues (Office Action at page 5). Application No. 09/618,432 issued as U.S. Patent No. 6,626,873 on September 30, 2003. For the Examiner's convenience, a copy of the issued claims are attached as Exhibit A.

### **The Claims Are Not Obvious**

Claims 1-9, 11-15, 17, 19-23, 26-30, 32-34 and 38-63 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable in view of U.S. Patent No. 6,261,271 to Solomon et al. ("Solomon").

As noted by the Examiner, Solomon discloses an anti-infective medical article that "has chlorhexidine bulk distributed throughout a polyurethane base layer and may have a coating on the base layer." *See* Abstract of Solomon (emphasis added). In particular, Solomon discloses that the optional coating may be achieved by steeping the article in a solvent solution of chlorhexidine. *See* Solomon, column 5 at lines 49-50.

The Examiner admits "Solomon does not disclose that the weight ratio[] of chlorhexidine free base to chlorhexidine salt is between 1:1 to 1:5." Office Action at page 5 (emphasis added). Nevertheless, the Examiner alleges that "both are contemplated by Solomon" and further opines that "those of ordinary skill would have found it within their skill to optimize the concentration of these known components of the solution of Solomon et al in order to obtain the coating which is instantly claimed." Office Action at page 5. Applicants respectfully disagree.

Indeed, Solomon does not disclose, suggest or “contemplate” treating a surface of a polymeric medical article with a solution of chlorhexidine free base and water-soluble chlorhexidine salt, which provides sustained anti-microbial effectiveness through an increased uptake of chlorhexidine into the medical article, as required by the pending claims. Nor does Solomon disclose or suggest medical articles that are prepared by such treatment. Accordingly, and especially in light of the Rule 132 Declaration of Dr. Modak, attached hereto, Applicants assert that the pending claims are not obvious in view of Solomon.

The Examiner also states that “[b]arring unexpected results, there is no[] showing that the claimed criticality is not a mere optimization of a known composition used for the same art recognized purpose. First, Applicants point out that the existence of unexpected results is a secondary consideration and only one factor to be considered in the underlying factual analysis in an obviousness inquiry. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Evidence indicating that unexpected results exist is typically used by an applicant to rebut a *prima facie* showing of obviousness. *In re Roufett*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). In order to show a *prima facie* case of obviousness, specific objective evidence must be presented demonstrating that the prior art would have taught or suggested to one of ordinary skill in the art how to make the claimed invention. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995). Applicants respectfully assert that the above allegations, at minimum, fail to state the requisite motivation to modify the disclosure of Solomon to reach the presently claimed invention, and thus do not constitute a *prima facie* case of obviousness. Therefore, absent a *prima facie* showing of obviousness, Applicants have no burden to demonstrate that the claimed invention stems from an unexpected finding.

Nevertheless, Applicants fully respond herein. Further, Applicants respond by submitting the attached Rule 132 Declaration, which evidences that the medical articles according to the pending claims demonstrated unexpectedly prolonged antimicrobial activity.

**The Claimed Antimicrobial Medical Articles Exhibit Unexpected Results**

As set forth in the attached Rule 132 Declaration, a medical article that has only been surface-treated as claimed by the instant invention would not have been expected by one of ordinary skill in the art to exhibit prolonged antimicrobial efficacy. Notably, Solomon's disclosure admits as much. Solomon specifically pointed out that by merely coating the surface of the medical device with chlorhexidine, one would observe a rapid release of the chlorhexidine from the surface. *See* Solomon, column 3 at lines 20-21. As presented in the attached Rule 132 Declaration, Dr. Modak's conclusions with respect to the level of skill in the art are fully consistent with Solomon's disclosure, which demonstrates that a person of ordinary skill in the art would not have expected microbial effectiveness of a chlorhexidine-coated medical article in the clinic and, therefore, would have had no reasonable expectation of success at the time of the present invention. Thus, both the attached Rule 132 Declaration and Solomon's own disclosure evidence that one of ordinary skill in the art at the time of the present invention could have only expected failure in preventing microbial infection when using such medical articles.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

Applicants respectfully request that the amendments and remarks herein be made of record. Applicants believe that in light of the foregoing amendments and remarks, the claims are in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding objections and rejections. An allowance is earnestly sought.

Respectfully submitted,

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Enclosures